RELEVANT EXCERPTS FROM THE CONSTITUTION OF THE UNITED STATES AND THE STATUTES

From Article I, Section 8 of the Constitution:

Clause 8. *The Congress shall have Power* * * * To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

* * * * * * * * * * *

From Article III of the Constitution:

SECTION 1. The judicial Power of the United States, shall be vested in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish.

* * * * * * * * * * *

From Title 5, U.S.C., Administrative Procedure Act:

§ 701. Application; definitions

(a) This chapter applies, according to the provisions thereof, except to the extent that—

(1) statutes preclude judicial review; or

(2) agency action is committed to agency discretion by law.

(b) For the purpose of this chapter—

(1) "agency" means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, but does not include—

(A) the Congress;

(B) the courts of the United States;

(C) the governments of the territories or possessions of the United States;

(D) the government of the District of Columbia;

(E) agencies composed of representatives of the parties or of representatives of organizations of the parties to the disputes determined by them;

(F) courts martial and military commissions;

(G) military authority exercised in the field in time of war or in occupied territory; or

(H) functions conferred by sections 1738, 1739, 1743, and 1744 of title 12; chapter 2 of title 41; or sections 1622, 1884, 1891-1902, and former section 1641(b)(2), of title 50, appendix; and

(2) "person", "rule", "order", "license", "sanction", "relief", and "agency action" have the meanings given them by section 551 of this title.

§ 702. Right of Review

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.

§ 703. Form and venue of proceeding

The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadquacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. Except to the extent that prior, adequate, and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement.

§ 704. Actions reviewable

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy

in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.

§ 705. Relief pending review

When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

FROM TITLE 21, U.S.C., FOOD AND DRUGS:

§ 372. Examinations and investigations—Authority to conduct

INFORMATION ON PATENTS FOR DRUGS

(d) The Secretary is authorized and directed, upon request from the Commissioner of Patents, to furnish full and complete information with respect to such questions relating to drugs as the Commissioner may submit concerning any patent application. The Secretary is further authorized, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required.

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FROM THE U.S. CODE, TITLE 28:

§ 211. Appointment and number of judges

The President shall appoint, by and with the advice and consent of the Senate, a chief judge and four associate judges who shall constitute a court of record known as the United States Court of Customs and Patent Appeals. Such court is hereby declared to be a court established under article III of the Constitution of the United States.

As amended Aug. 25, 1958, Pub.L. 85-755, § 1, 72 Stat. 848.

* * * * * * * * * *

§ 1291. Final decisions of district courts

The courts of appeals shall have jurisdiction of appeals from all final decisions of the district courts of the United States, . . . except where a direct review may be had in the Supreme Court. June 25, 1948, c. 646, 62 Stat. 929; Oct. 31, 1951, c. 655, § 48, 65 Stat 726; July 7, 1958, Pub.L. 85-508, § 12(e), 72 Stat. 348.

§ 1338. Patents, plant variety protection, copyrights, trade-marks, and unfair competition

(a) The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents. . . . Such jurisdiction shall be exclusive of the courts of the states in patent, . . . cases.

§ 1361. Action to compel an officer of the United States to perform his duty

The district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff.

§ 1391. Venue generally

(e) A civil action in which each defendant is an officer or employee of the United States or any agency thereof act-

ing in his official capacity or under color of legal authority, or an agency of the United States, may, except as otherwise provided by law, be brought in any judicial district in which: (1) a defendant in the action resides, or (2) the cause of action arose or (3) any real property involved in the action is situated, or (4) the plaintiff resides if no real property is involved in the action. . . .

§ 1393. Divisions; single defendant; defendants in different divisions

(a) Except as otherwise provided, any civil action, not of a local nature, against a single defendant in a district containing more than one division must be brought in the division where he resides. . . .

§ 2107. Time for appeal to court of appeals

Except as otherwise provided in this section, no appeal shall bring any judgment, order or decree in an action, suit or proceeding of a civil nature before a court of appeals for review unless notice of appeal is filed, within thirty days after the entry of such judgment, order or decree.

In any such action, suit or proceeding in which the United States or an officer or agency thereof is a party, the time as to all parties shall be sixty days from such entry.

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FROM THE U.S. CODE, TITLE 35:

§ 1. Establishment

The Patent Office shall continue as an office in the Department of Commerce, . . . July 19, 1952, c. 950, § 1, 66 Stat. 792.

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§ 6. Duties of Commissioner

The Commissioner, under the direction of the Secretary of Commerce, shall superintend or perform all duties required by law respecting the granting and issuing of patents

and the registration of trade-marks; . . . He may, subject to the approval of the Secretary of Commerce, establish regulations, not inconsistent with law, for the conduct of proceedings in the Patent Office. July 19, 1952, c. 950, § 1, 66 Stat. 793.

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§ 7. Board of Appeals

The examiners-in-chief shall be persons of competent legal knowledge and scientific ability. The Commissioner, the assistant commissioners, and the examiners-in-chief shall constitute a Board of Appeals, which, on written appeal of the applicant, shall review adverse decisions of examiners upon applications for patents. Each appeal shall be heard by at least three members of the Board of Appeals, the members hearing such appeal to be designated by the Commissioner. The Board of Appeals has sole power to grant rehearings.

Whenever the Commissioner considers it necessary to maintain the work of the Board of Appeals current, he may designate any patent examiner of the primary examiner grade or higher, having the requisite ability, to serve as examiner-in-chief for periods not exceeding six months each. An examiner so designated shall be qualified to act as a member of the Board of Appeals. Not more than one such primary examiner shall be a member of the Board of Appeals hearing an appeal. July 19, 1952, c. 950, § 1, 66 Stat. 793.

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§ 112. Specification

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. A claim may be written in independent or dependent form, and if in dependent form, it shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. . . . As amended July 24, 1965, Pub.L. 89—83, § 9, 79 Stat. 261.

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§ 131. Examination of application

The Commissioner shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Commissioner shall issue a patent therefor. July 19, 1952, c. 950, § 1, 66 Stat. 801.

§ 132. Notice of rejection; reexamination

Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Commissioner shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention. July 19, 1952, c. 950, § 1, 66 Stat. 801.

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§ 141. Appeal to Court of Customs and Patent Appeals

An applicant dissatisfied with the decision of the Board of Appeals may appeal to the United States Court of Customs and Patent Appeals, thereby waiving his right to proceed under section 145 of this title. . . . July 19, 1952, c. 950, § 1, 66 Stat. 802.

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§ 145. Civil action to obtain patent

An applicant dissatisfied with the decision of the Board of Appeals may unless appeal has been taken to the United States Court of Customs and Patent Appeals, have remedy by civil action against the Commissioner in the United States District Court for the District of Columbia if commenced within such time after such decision, not less than sixty days, as the Commissioner appoints. The court may adjudge that such applicant is entitled to receive a patent for his invention, as specified in any of his claims involved in the decision of the Board of Appeals, as the facts in the case may appear and such adjudication shall authorize the Commissioner to issue such patent on compliance with the requirements of law. . . . July 19, 1952, c. 950, § 1, 66 Stat. 803.

* * * * * * * * * *

OPINION OF THE COURT OF APPEALS
DATED DECEMBER 3, 1974

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 74-1136

RHONE-POULENC S.A., DENISE MANCY, LEON NINET and JEAN PREUD' HOMME, *Appellants,*

v.

C. MARSHALL DANN, Commissioner of Patents, *Appellee.*

Appeal from the United States District Court for the Eastern District of Virginia, at Alexandria.

Albert V. Bryan, Jr., District Judge

Argued October 2, 1974. Decided December 3, 1974.

Before HAYNSWORTH, *Chief Judge,* and RUSSELL and FIELD, *Circuit Judges.*

Ellsworth H. Mosher (Charles A. Wendel on brief) for Appellants;

Fred W. McKelvey, Associate Solicitor, United States Patent Office, (Joseph F. Nakamura, Solicitor, United States Patent Office, on brief) for Appellee.

Per Curiam:

Rhone-Poulenc is a French corporation which, along with several scientists, is seeking to patent a new process for preparing a known antibiotic drug, daunorubicin. The Primary Examiner determined that all claims in the ap-

plication, Serial No. 775,904, are allowable but objected to the application because of the presence of certain words in the specification. The paragraph containing the disputed phrase reads as follows:

> *S. griseus, var. rubidofaciens, strain DS 32,041* differs from the species distinguished by S. A. Waksman within the series of the strains of *S. griseus*, of which none of those hitherto described gives a soluble red pigment comparable to that produced by the strain DS 32,041 nor gives any production of antibiotic and anti-tumour substance identical to daunorubincin * * *.

Specifically, the Primary Examiner objected to the words "and anti-tumour" and required either "cancellation of said term or proof that the instant compound is safe, reliable and effective for the utility set forth * * *." Considerable evidence was adduced, which the Commissioner concedes is sufficient to support a conclusion that daunorubicin has an anti-tumour effect in treating certain tumors, namely lymphosarcoma, nephroblastoma, neuroblastoma, acute lymphoblastic leukemia, and acute myeloblastic leukemia. The Primary Examiner adhered to his requirement that the phrase be stricken because it was broader than the proof offered in support. The applicants sought review in the Patent Office and ultimately in the District Court, which sustained the cancellation requirement.

The Commissioner is granted authority to restrict the specification so that it is not overbroad. Indeed,

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C.A. § 112. The Commissioner has gone beyond his interpretation of the disputed words, however, to reject amending language that would restrict the assertion to those uses supported by the proof. It is suggested that such an amendment would be "new matter," the introduction of which is precluded by 35 U.S.C.A. § 132. We do not view such words of limitation as new matter. "Amendments to specifications for the purpose of clarity and definiteness are permissible." *Helms Products, Inc.* v. *Lake Shore Manufacturing Co.*, 7 Cir. 227 F.2d 677, 679. *See also Aerosol Research Co.* v. *Scovill Manufacturing Co.*, 7 Cir., 334 F.2d 751.

We therefore conclude that the concellation of the words "anti-tumour" by the Patent Office was arbitrary and capricious and reverse the decision of the District Court. The cancellation requirement is set aside with leave to the Commissioner to allow an amendment restricting the specification to assertions that are supported by the applicants' proof.[1]

Reversed and Remanded.

ORDER OF THE COURT OF APPEALS DENYING REHEARING DATED JANUARY 30, 1975

(Caption Omitted in Printing)

ORDER

Upon consideration of the petition of the Commissioner for rehearing and for revision of the opinion, it appearing from the proposal included in the petition that counsel for the petitioner clearly understands the Court's intention, and upon consideration of the appellants' petition for rehearing,

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[1] We note, and counsel for the appellee acknowledged at oral argument, that the applicants could refile their application with an amended specification, thereby retaining their filing date and accomplishing the same result.

Now, therefore, with the concurrence of Judges Russell and Field, IT IS ORDERED that the petitions be, and hereby are denied.

/s/ CLEMENT F. HAYNSWORTH
Chief Judge, Fourth Circuit

January 30, 1975

MEMORANDUM OPINION AND ORDER OF THE DISTRICT COURT DATED NOVEMBER 1, 1973

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

Civil Action No. 168-73-A

RHONE-POULENC S.A., *et al., Plaintiffs,*

v.

ROBERT GOTTSCHALK, etc., *Defendant.*

Memorandum Opinion and Order

This is an action under the Administrative Procedures Act, 5 U.S.C. § 701, *et seq.*, to review a decision of the Commissioner of Patents. The plaintiffs are the applicants and their assignee for a patent, No. 775,904 entitled "New Process for the Preparation of Daunorubicin."

The application was filed on November 14, 1968. The Patent Office has allowed all twelve claims contained in the application, but the Commissioner of Patents has sustained an Examiner's action in requiring that the words "and anti-tumour" be deleted from page 9 of the specification of the patent. The text in which these words appear is as follows:

> *S. griseus, var. rubidofaciens,* strain DS 32,041 differs from the species distinguished by S. A. Waksman

with the series of the strains of *S. griseus*, of which none of those hitherto described gives a soluble red pigment comparable to that produced by the strain DS 32,041 nor gives any production of antibiotic and antitumour substance identical to daunorubicin (The Actinomycetes, Vol. II, S. A. Waksman, the Williams and Wilkins Company, Baltimore, 1961, pages 140-143).

That action of the Commissioner is the subject of this review. There is no other adequate remedy, since this particular action of the Commissioner does not relate to the patentability of the claims and consequently is not reviewable by the Board of Appeals, 35 U.S.C. § 134; the United States Court of Customs and Patent Appeals, 35 U.S.C. § 141; or the United States District Court for the District of Columbia, 35 U.S.C. § 145.

The Commissioner has filed a Motion to Dismiss, and plaintiffs and the Commisisoner have filed cross motions for summary judgment. Both sides agree that if the motion to dismiss is not granted that all relevant evidence is before the Court in the form of exhibits 1-4 and the exhibits attached to the defendant's motion, and that the case is, in that event, a proper one for summary judgment on the record. In addition, the parties agree that in considering the motions for summary judgment, the standard by which the Commissioner's action is to be measured is whether it was "arbitrary, capricious, [or] an abuse of discretion ...." 5 U.S.C. § 706(2)(A).

The motion to dismiss is based on (1) lack of subject matter jurisdiction, and (2) failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(1) and (6). The Court has jurisdiction under 28 U.S.C. § 1361 to compel the defendant Commissioner of Patents to perform a duty owed the plaintiff—a duty allegedly violated by that defendant's arbitrary and capricious action. Review of that action is, of course, allowed by the Administrative Procedure Act, *supra*. The complaint adequately

alleges an arbitrary, capricious final decision of the agency for which there is no adequate remedy other than judicial. It also alleges damage. This is sufficient to state a claim. The motion to dismiss is accordingly denied.

Turning to the motions for summary judgment—the Commissioner's decision was based on the Examiner's conclusion that "the expression 'anti-tumour' encompasses the treatment of all types of cancer . . . ." Literally of course this is true, although the Court, were it to consider the matter *de novo*, would be hard put to find that anyone skilled in the art would view the phrase so technically. It would seem more reasonable, in the context in which the phrase appears, to conclude that the phrase meant no more than the substance had different properties which deter some tumours than the substance and species from which the invention was sought to be distinguished, described in the first part of the paragraph. The defendant argues that there has been no proof that the substance is an anti-tumour agent for all or a wide variety of tumours. This discussion is really irrelevant. The plaintiffs have never contended that the substance is effective for all types of tumours. The issue is whether a person skilled in the art to which the patent pertains would be misled. This and whether the phrase constitutes the "full, clear, concise, and exact . . ." "description of the invention" required by 15 U.S.C. § 112, are matters better left to the discretion of the Patent Office. Concluding that the phrase was overbroad, with that conclusion now supported by the Food and Drug Administration's like conclusion (although the inquiry to that body may have "begged the question" by the manner in which the inquiry was phrased) cannot be considered arbitrary and capricious even though this Court might not agree with that conclusion.

The plaintiffs' fears of a file wrapper estoppel operating against them seem groundless. They can hardly be accused at a later date with acquiescing in the Commissioner's

position or abandoning his claim that the substance has some anti-tumour properties, in view of their repeated efforts in the Patent Office and their action here attempting to retain in the patent language to that effect.

Summary judgment is awarded the defendant; and it is so ordered.

/s/A. V. B. Jr.
United States District Judge

Alexandria, Virginia

November 1st, 1973

FROM THE PATENT OFFICE ACTION OF APRIL 1, 1971

In view of the decision in In re Argoudelis et al., 168 U.S.P.Q. 99, applicants are required to aver:

(1) that all restrictions on availability of the culture deposit to the public will be irrevocably removed on the granting of the patent, and

(2) that the culture will be maintained by the depositor throughout the effective life of the patent.

The claims remain under rejection for insufficient disclosure under 35 U.S.C. 112, for reasons set forth on page 4 in the Office Action dated January 21, 1970. Compliance with the above will obviate this ground of rejection.

Claims 1-12 are rejected as indefinite and for failing to particularly point out and distinctly claim the invention as required in 35 U.S.C. 112 for reasons set forth in the Office Action of January 21, 1970. The characteristics of daunorubicin are believed essential and therefore should be set forth. For the incorporation of essential material see M.P.E.P. 608.01(p).

Claims 1-12 are rejected as unpatentable over the patent to Rhone-Poulenc under 35 U.S.C. 103 for reasons set forth in the Office Action of January 21, 1970. Applicants argue that the instant compound is produced by a microorganism that is different than shown by Rhone-Poulenc. However,

no comparison has been made with the instant microorganism. Also, since both microorganisms are classified as Streptomyces, it is believed obvious, under the Statute, to use another Streptomyces species, even though a screening process may be needed.

All the claims are rejected for lack of utility under 35 U.S.C. 101 for reasons set forth in the Office Action of January 21, 1970. Applicants contend that the instant compound has utility as an antibiotic and anti-tumor substance. It is believed some evidence to that extent should be presented. Applicants' citation of several articles to show the structure and utility of the instant compound is noted, however, it is believed such should be part of the application, as filed, to satisfy the Statute.

No claim is allowed.

This rejection is made FINAL.

/s/ ALBERT T. MYERS
Albert T. Myers
Examiner Group Art
Unit 125

FROM THE PATENT OFFICE ACTION OF NOVEMBER 7, 1972

☐ This application has been examined.

☒ Responsive to communication filed Dec. 1, 1971.

☐ This action is *made final.*

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS ACTION IS SET TO EXPIRE TWO MONTHS FROM THE DATE OF THIS LETTER.

PART I

The Following attachment(s) are part of this action:

a. ☐ Notice of References Cited, From PO-892.

b. ☐ Notice of Informal Patent Drawing PO-948.

c. ☐ Notice of Informal Patent Application, Form PO-152.

d. ☐

PART II

Summary of Action

1. ☒ Claims 1-12 are presented for examination.
2. ☒ Claims 1-12 are allowed.
3. ☐ Claims ——— would be allowable if amended as indicated.
4. ☐ Claims ——— are rejected.
5. ☐ Claims ——— are objected to.
6. ☐ Claims ——— are subject to restriction or election requirement.
7. ☐ Claims ——— are withdrawn from consideration.
8. ☒ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 OG. 213.

The following changes have been agreed to between Ellsworth H. Mosher, Esquire and the Examiner during a telephone conversation on September 13, 1972.

In claim 1, lines 3 and 4, the term "or a daunorubicin-producing mutant thereof, using" to be cancelled, the term "in" to be inserted before the term "an" in line 4, and the term "until sufficient amount of the antibiotic is produced," to be inserted before the term "and" in line 6.

The specification is objected to with regard to the term "and anti-tumour" on page 9. Cancellation of said term or proof that the instant compound is safe, reliable and effective for the utility set forth is in order. See In re Gottlieb, 140 U.S.P.Q. at page 668.

/s/ ALBERT T. MYERS
Albert T. Myers
Examiner Group Art
Art Unit 125

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FROM THE COMMISSIONER'S DECISION ON PETITION, DATED MARCH 21, 1973

Petitioners have filed two petitions labelled I and II requesting the exercise of supervisory authority by (I) reversing the examiner's holding that the amendment of January 8, 1973 is an incomplete response and (II) reversing the examiner's requirement to cancel the utility relating to anti-tumour activity.

The petitions will be treated in that order.

I. The examiner is instructed to accept and enter the amendment of January 8, 1973 in spite of the fact it does not cancel objectionable subject matter. Petitioners are permitted to ask reconsideration of the examiner's requirement at this stage prior to taking a petition since the requirement to cancel was first made in the Office action of November 7, 1972.

II. This petition relates to the examiner's requirement to cancel all reference to the unproven anti-tumour activity. In spite of the petitioners' argument, the record of this application and the application of Pinnert et al have not been found to adequately prove the anti-tumour use as required by the present standards. Thus In re Gottlieb et al 140 USPQ 665 is believed in point. Further petitioners are referred to the Guidelines for Disclosures of Utility in Drug Cases 849 O.G. 567, last full paragraph. Thus there is no abuse of discretion in the examiner's requirement to cancel that warrants supervisory intervention and the petition must be denied.

Since petitioners have chosen the petition route rather than cancel, they are given thirty (30) days from the date of this decision to either cancel the objectionable subject matter or seek appropriate court review. (Section 1002.02 Manual of Patent Examining Procedure) to avoid a holding of abandonment.

The Petition as to entry of the amendment is Granted and the Petition as to the requirement to cancel objectionable subject matter is Denied.

/s/ Irving Marcus
Irving Marcus, *Director*
Patent Examining Group 120
Organic and Medicinal Chemistry

CORRECTION OF COMMISSIONER'S OPINION, UNDER DATE OF AUGUST 8, 1973

On March 21, 1973, a decision was rendered on a petition [Petition to the Commissioner (II)] filed in the above-identified application.

A paragraph of the opinion in support of the decision on petition reads:

> "Since petitioners have chosen the petition route rather than cancel, they are given thirty (30) days from the date of this decision to either cancel the objectionable subject matter or seek appropriate court review. (Section 1002.02 Manual of Patent Examining Procedure) to avoid a holding of abandonment."

That paragraph should have read, and is hereby corrected to read:

> "Since petitioners have chosen the petition route rather than cancel, they are given thirty (30) days from the date of this decision to either cancel the objectionable subject matter or seek appropriate court review. (Section 1002.02, Manual of Patent Examining Procedure.). If petitioners do not cancel the objectionable subject matter or seek appropriate court review within the thirty (30) day period set herein, the examiner is instructed to cancel the objectionable subject matter and pass the application to issue."

Since petitioners have sought judicial review, further prosecution is suspended pending the outcome of Civil Ac-

tion No. 168-73-A, *Rhone-Poulenc, S.A. et al. v. Gottschalk* (E.D. Va. 1973).

/s/ Irving Marcus
Irving Marcus, *Director*
Patent Examining Group 120
Organic and Medicinal Chemistry

FROM THE PATENT OFFICE LETTER FOR THE FILE, DATED AUGUST 21, 1973, WITH EXHIBIT A (LETTER OF JULY 13, 1973 TO F.D.A.) AND EXHIBIT B (F.D.A.'S REPLY OF AUGUST 9, 1973)

On July 13, 1973, the above-identified application was forwarded to the Food and Drug Administration in the Department of Health, Education, and Welfare for review under Public Law 87-781 (21 U.S.C. 372). See Exhibit A.

A response from the Food and Drug Administration was received on August 9, 1973. See Exhibit B.

Exhibits A and B are hereby made of record in the file of the above-identified application.

/s/ Albert T. Myers
Albert T. Myers
Supervisory Primary Examiner
Art Unit 125

Exhibit A, Dated July 13, 1973:

To: Mr. Theodore Byers, Director, Office of Compliance, Food and Drug Administration

From: Mr. Irving Marcus, Director, Chemical Examining Group 120

Subject: FDA Review of Patent Applications

It is requested under the provisions of Public Law 87-781 (21 U.S.C. 372) that an evaluation of the indicated subject matter be provided by your Office.

Enclosed are copies of the following pertinent papers of record in application, Serial No. 775,904, filed November 14, 1968 by Mancy et al.

1. Paper No. 1—Application papers filed November 14, 1968
2. Paper No. 4—Applicants' amendment and exhibit filed April 21, 1970
3. Paper No. 10—Applicants' amendment filed June 28, 1971
4. Paper No. 20—Applicants' Petition to the Commissioner (II) filed March 14, 1973
5. Paper No. 21—Commissioner's Decision of March 21, 1973

Additionally enclosed are copies of the following pertinent papers from a related application, Serial No. 280,816, filed May 16, 1963 by Pinnert et al.

1. Paper No. 5—Declaration of Jacquillat and exhibits filed April 15, 1966
2. Paper No. 8½—Applicants' amendment and exhibits filed June 6, 1968

Still further, there is enclosed a book entitled "Rubidomycin," Edited by Bernard et al., published in 1969.

The application involved (Serial No. 775,904) claims a method for making daunorubicin. In addition to claiming that method, the specification discloses that daunorubicin is an "anti-tumour substance" (see page 9, line 15 of the application papers of Serial No. 775,904). The specification does not mention any specific type of tumor.

In support of their contention that daunorubicin is an anti-tumor substance, applicants have submitted various documents identified above.

Application Serial No. 775,904 is involved in a civil action. *Rhone-Poulenc S.A.* v. *Gottschalk, Commissioner of Patents,* Civil Action No. 168-73-A (E.D. Va., Filed April 19, 1973). Accordingly, your prompt answer to the following query is solicited.

Query—Is there sufficient evidence of record to permit one skilled in the art to conclude that daunorubicin is an "anti-tumor substance"?

Exhibit B, Dated August 9, 1973:

Mr. Irving Marcus
Director, Chemical Examining Group 120
U.S. Department of Commerce
Patent Office
Washington, D.C. 20231

Dear Mr. Marcus:

In response to your request for review of patent applications of July 13, 1973 regarding Daunorubicin (Rubidomycin), the following comments are offered:

As you may know, under The Federal Food, Drug, and Cosmetic Act, a drug must have a New Drug Application approved by the Food and Drug Administration to establish its safety and efficacy for its intended uses prior to commercial marketing. Also, all clinical investigations must be conducted under a valid Investigational New Drug Application on file with the FDA.

A search of our records fails to show either an investigational new drug application or an approved new drug application on file for Daunorubicin. Consequently, the FDA cannot state with certainty whether daunorubicin is, in fact, safe and effective as an "anti-tumor substance."

While we would regard the term "anti-tumor substance" to be broad since we are unaware of any drug that would be effective for *all* types of tumors, a review of the avail-

able information indicates that daunorubicin has shown a few good responses in lymphosarcoma, nephroblastoma, and neuroblastoma. Also the drug may be regarded as effective in initiating remissions in acute lymphoblastic leukemia and acute myeloblastic leukemia.

Daunorubicin is not indicated for maintenance therapy or for treatment of chronic leukemia, and toxicity is primarily bone marrow and cardiac toxicity.

The reports on which this information is primarily based are mainly French and English as the American experience has been primarily with daunomycin, which is said to be identical to rubidomycin although obtained differently in Italy.

We hope you will find the above information helpful; and, if we can be of further assistance, please let us know.

Sincerely yours,

/s/ T. E. Byers
T. E. Byers, *Director*
Office of Compliance
Bureau of Drugs

RHONE-POULENC'S LETTER TO THE COURT OF APPEALS (WITH ATTACHED PROPOSED STIPULATION) FOLLOWING THE ORAL ARGUMENT THEREIN

October 11, 1974

United States Court of Appeals
Fourth Circuit
Tenth and Main Streets
Richmond, Virginia 23219

Re: Rhone-Poulenc S. A. et al v. C. Marshall Dann, Commissioner of Patents No. 74-1136

To the Honorable, the Chief Judge and Circuit Judges Russell and Field:

It will be recalled that during the oral argument of the appeal on October 2, 1974 before this panel of the Court, there came a time during the argument when the Court suggested to counsel for the parties that perhaps they could get together in the very near future and devise some mutually satisfactory language of intermediate scope that would be acceptable as a reasonable compromise for the disputed terminology. The Court suggested that a period of about two weeks could be afforded the parties to try to work out some such agreement and report back to the Court.

Pursuant to that direction by the Court, counsel for the appellants prepared a proposed Stipulation Between the Parties, and Order of the Court Based Thereon, in Settlement of this Appeal and presented same to counsel for the appellee to be used as the basis for initiating the discussion between counsel suggested by the Court. For the information of the Court, and to insure that the entire prosecution of the patent application which is the subject of this appeal shall be conveniently available to the public, copies of the Stipulation Between the Parties, and Order of the Court Based Thereon, in Settlement of this Appeal are attached hereto so that it can be made a part of the official record of the case if the Court so chooses.

Counsel for the appellee courteously afforded counsel for the appellants full opportunity for such discussion based on the proposed Stipulation. During that discussion it was suggested that it might be desirable to include the word "certain" or "some" before the word "tumors" in the double-underscored portion shown in Section 2 of the Stipulation. Counsel for the appellants indicated that this probably would be agreeable to the overseas appellants, but decided thereafter not to actually refer the matter to the appellants until such time, if any, as an agreement in overall principle could be reached.

The aforesaid discussion between counsel referred to above took place on Wednesday, October 9, 1974. On Thursday October 10, 1974, counsel for the appellee telephoned counsel for the appellants to state that after due consideration the appellee could not agree to the stipulation.

It therefore appears that it would be in order for the Court at this time to treat the appeal as submitted on the briefs and oral arguments already presented to the Court.

Respectfully submitted,

/s/ Ellsworth H. Mosher
Ellsworth H. Mosher
Attorney for the Appellants

EHM:mmh
Attachment

cc: Hon. Fred E. McKelvey
Associate Solicitor,
U.S. Patent Office
Attorney for the Appellee

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 74-1136

RHONE-POULENC S.A., et al, *Appellants,*

v.

C. MARSHALL DANN, Commissioner of Patents, *Appellee.*

STIPULATION BETWEEN THE PARTIES, AND ORDER OF THE COURT BASED THEREON, IN SETTLEMENT OF THIS APPEAL

Now come the parties to this appeal this day of October, 1974, and for the purpose of settling this appeal without further delay, and subject to the approval of this Court, stipulate and agree between themselves as follows:

1. This Court has jurisdiction over the parties to this appeal and over the subject matter thereof;

2. The parties accept a revised text of the specification of the patent application involved in this appeal for the paragraph at page 9, including the heretofore disputed line 15, as and in the manner shown by the following, where the words to be deleted are shown within brackets [] and the words to be added are DOUBLE-UNDERSCORED.

> "*S. griseus, var. rubidofaciens, strain DS 32,041* differs from the species distinguished by S. A. Waksman within the series of the strains of *S. griseus*, of which none of those hitherto described gives a soluble red pigment comparable to that produced by the strain DS 32,041 nor gives any production of antibiotic [and anti-tumour] substance WHICH HAS BEEN FOUND USEFUL FOR TREATING PATIENTS AFFECTED BY TUMORS AND IS identical to daunorubicin (The Actinomycetes, Vol. II, S. A. Waksman, The Williams and Wilkins Company, Baltimore, 1961, pages 140-143)."

3. Upon approval of this Stipulation by this Court, the Memorandum Opinion and Order of the United States Court for the Eastern District of Virginia, Alexandria

Division, dated November 1, 1973, shall be vacated as moot, following the precedent of the Supreme Court of the United States in *Brenner, Commissioner of Patents* v. *Hofstetter*, 389 U.S. 5 (1967).

4. The principle of this Stipulation and Order shall apply to and be binding on the parties hereto in all other pending or future United States patent applications filed and/or owned by the corporate appellant Rhone-Poulenc, S.A., where a similar requirement is made (or would otherwise be made) by the appellee Commissioner of Patents with respect to an allegation of anti-tumour activity.

5. In the event of any future dispute between the parties as to the operation and applicability of paragraph 4 with respect to any other Rhone-Poulenc U.S. application, either party shall be at liberty to apply directly to this Court for appropriate relief, and this Court will itself settle and determine the dispute or in its discretion will refer the dispute to the Court below for a ruling.

6. This appeal shall be dismissed with prejudice, except as to the matters left open for the future in paragraphs 4 and 5 hereof.

JOSEPH F. NAKAMURA
Solicitor
United States Patent Office

FRED E. MCKELVEY
Associate Solicitor
United States Patent Office
Attorneys for Appellee

/s/ ELLSWORTH H. MOSHER
Ellsworth H. Mosher
/s/ CHARLES S. WENDEL
Charles S. Wendel
Attorneys for the Appellants

* * * * * * * * * *

Let the foregoing be entered as the Order of this Court, this day of October, 1974.

.....
Judge
United States Court of Appeals
for the Fourth Circuit
(For the Court)

THE COMMISSIONER'S LETTER OF REPLY, DATED OCTOBER 15, 1974

U.S. DEPARTMENT OF COMMERCE
PATENT OFFICE

United States Court of Appeals
for the Fourth Circuit
10th & Main Streets
Richmond, Virginia 23219
Re: Rhone-Poulenc S.A. v. Dann
Appeal No. 74-1136
Oral hearing on October 2, 1974, before
Haynsworth Chief Judge, and Russell
and Field, Circuit Judges

As indicated in appellant's letter dated October 11, 1974, the parties in accordance with the request of the Court at oral hearing attempted again to settle the case.

Inasmuch as appellant's offer of settlement has been placed before the Court, the Commissioner makes the following brief comments.

The proposed language in paragraph 2 of the offer of settlement is just as broad as the language presently in the application on appeal and, in addition, refers to "patients." The proposed language, therefore, poses as does the present language, the same "imprimature" problem, mentioned by Judge Field at the hearing and discussed in *Isenstead* v. *Watson,* cited in appellee's brief.

Paragraph 4 of appellant's offer is objectionable, because each application in the Patent Office must be judged on its own merits. Moreover, the Court should be aware of the fact that prosecution on several applications, including

some not owned by appellant, has been suspended pending outcome of this appeal.

Paragraph 5 attempts to give the Court arbitration jurisdiction over the parties; only Congress may establish the jurisdiction of the federal courts, apart from the Supreme Court; Constitution, Article III, Section 1.

At the hearing, the Chief Judge suggested that the language in the specification of the application on appeal might be amended to conform to the evidence. Unfortunately, such an amendment is not believed possible in this case in view of the provisions of 35 U.S.C. § 132, last sentence. A generic disclosure in a patent application does not necessarily provide a basis for an amendment to incorporate a sub-generic disclosure. In this respect, the Court may be interested in *Application of Smith,* 59 CCPA 1025, 458 F.2d 1389 (CCPA 1972); *Watson* v. *Bersworth,* 102 U.S. App. D.C. 187, 251 F.2d 898 (D.C. Cir. 1958); *In re Mraz,* 36 App. D.C. 435 (D.C. Cir. 1911).

Inasmuch as it has not been possible to settle the case, the Court may consider the case submitted.

Respectfully submitted,

Dated: Oct. 15, 1974

/s/ JOSEPH F. NAKAMURA
Joseph F. Nakamura
Solicitor
United States Patent Office

/s/ FRED E. MCKELVEY
Fred E. McKelvey
Associate Solicitor
United States Patent Office

October 15, 1974

cc: Ellsworth H. Mosher, Esq.
Stevens, Davis, Miller & Mosher
Suite 600, Crystal Mall 1
1911 Jefferson Davis Highway
Arlington, Va. 22202

RHONE-POULENC'S RESPONSE, DATED OCTOBER 16, 1974

LAW OFFICES OF
STEVENS, DAVIS, MILLER & MOSHER
1911 JEFFERSON DAVIS HIGHWAY
SUITE 600 CRYSTAL MALL 1
ARLINGTON, VIRGINIA 22202

TELEPHONE (703) 920-8900

October 16, 1974

United States Court of Appeals
Fourth Circuit
Tenth and Main Streets
Richmond, Virginia 23219

Re: Rhone-Poulenc S.A. et al
v. C. Marshall Dann,
Commissioner of Patents
No. 74-1136

TO THE HONORABLE, THE CHIEF JUDGE AND
CIRCUIT JUDGES RUSSELL AND FIELD:

Appellants are both surprised and astonished at appellee's letter to the Court, dated October 15, 1974, in response to appellants' letter of October 11, 1974. Appellants took great care to couch their letter in perfectly straightforward and factual terms setting forth *what* they believed themselves to be entitled to via their proposed STIPULATION, while studiously avoiding the *why*. Appellants are therefore taken by surprise at any supposed need for a reply.

Assuming, however, need for such a reply, appellants are astonished at the contents, which appear more nearly to resemble a further briefing effort. In the absence of any "why" in appellants' letter, there would appear to be little or no excuse for a "why not" response from the appellee. But since the appellee did in fact thus respond, appellants deem it necessary to present this short explanation of their "why":

Paragraph 1 of the proposed STIPULATION is self-explanatory.

So, too, is Paragraph 2. The appellee's criticism of the word "patients" is puzzling and appears to be the merest quibble. The ordinary dictionary definition of patient is "a sick person". Does the appellee seriously suggest that one afflicted with cancer (tumor) is not a sick person, and therefore not a patient? In any event, the record shows that the word "patients" has long since been used by appellants without any previous objection on the part of appellee—e.g., J.A. 52, 72.

Paragraph 3 is self-explanatory.

Paragraph 4 was intended for the obvious purpose of avoiding the necessity, if an agreement in principle satisfactory to all concerned could have been reached, for appellants to take each and every one of their other patent applications presenting essentially the same issue right back through the courts again. This paragraph was carefully limited to extend only to such of *appellants'* other patent applications, if any, where "a *similar* requirement is made (or would otherwise be made) by the appellee, etc." Any problems the appellee may be currently having with patent applications "not owned by appellant[s]" cannot rightly be of any legitimate concern to the appellants because of the confidential status imposed by statute on such other applications (35 U.S.C. § 122), to say nothing of the fact that the owners of such other applications are not before this Court.

Paragraph 5 of the proposed STIPULATION was intended to insure that despite the protection afforded appellants by Paragraph 4, the Patent Office would nevertheless have a convenient and speedy remedy in the event the appellants should in the future take what might seem to the Patent Office to be an unreasonable position on the issue in question in any of their other patent applications. There was no thought of any attempt to give the Court "arbitration

jurisdiction over the parties", whatever that may mean. Surely it is hornbook law that where, as here, a Court has jurisdiction over the parties before it and of the subject matter involved (see Paragraph 1 of the proposed STIPULATION to which no objection was made in appellee's letter), that Court has ample authority to pattern a remedial order in such fashion as to foreclose the possibility of the same or substantially same issue ever arising between *those same parties that are before the Court* in any other guise.

The citation of the new cases (*Smith, Bersworth* and *Mraz*) on page 2 of the appellee's letter would appear to justify the reference to "a further briefing effort" earlier in the present letter. The relevance of these newly cited cases is not apparent. All three cases involved the question of whether a given disclosure could be accepted in justification of the allowability of claims that all along had been *rejected* by the Patent Office. In the present case, it should not be forgotten that appellants' claims have long since been *allowed* by the Patent Office. But if this Court should be "interested" in those three cases, the Court might also be interested in a couple of cases from still higher authority. The Supreme Court of the United States has made it clear (*Diamond Rubber Co.* v. *Consolidated Rubber Tire Co.*, 220 U.S. 428 (1911)) that it does not take from the merit of an inventor that he may not know all of the forces that he has brought into operation by his invention (p. 435), and that it is immaterial whether the principle upon which it acts be obvious or obscure so long as it is inherent (p. 436). Still earlier, the Supreme Court had taught (*The Telephone Cases*, 126 U.S. 1 (1888)) that where an inventor had described his process in his specification accurately and with sufficient clearness to enable one of ordinary skill in the art how to achieve the desired result, this was sufficient even though at the time the inventor applied for his patent he himself had not yet actually achieved that result (pp. 535-6). The appellants here

are obviously in an even more favorable position than was Grant in *Diamond Rubber* or Bell in *The Telephone Cases*, where in each instance the patent was sustained.

Or as the older cases (e.g., *Corning* v. *Burden*, 15 How. (U.S.) 252, 259 (1853); *Turrill* v. *Michigan Southern R.R. Co.*, 1 Wall (68 U.S.) 491, 510 (1863)) were wont to put it: "ut res magis valeat quam pereat"!

Respectfully submitted,

/s/ ELLSWORTH H. MOSHER
Ellsworth H. Mosher
Attorney for the Appellees

EHM: mmh
cc: Hon. Fred E. McKelvey
Associate Solicitor
U. S. Patent Office
Attorney for the Appellee

THE COMMISSIONER'S PETITION FOR REHEARING IN THE COURT OF APPEALS, WITH ATTACHED APPENDIX I

* * * * * * * * * *

(Caption omitted in Printing)

The Commissioner of Patents respectfully petitions, under the provisions of Rule 40 of the Federal Rules of Appellate Procedure, for reconsideration, and alternatively, for clarification of the decision in this appeal rendered on December 3, 1974.

The point which is thought to have been overlooked and which requires reconsideration is whether, under the facts of this case, appellants suffer any legal harm because of the Commissioner's action in requiring cancellation of the language "and anti-tumour" from the specification of appellants' patent application.

Assuming the Court did not overlook the above-mentioned point, the Commissioner nevertheless believes clarification of the Court's opinion is desirable.

1. The Court's Opinion

The Court, in its opinion, recognized that the Commissioner believes the evidence supports "a conclusion that daunorubicin has an anti-tumour effect in treating certain tumors, namely lymphosarcoma, nephroblastoma, neuroblastoma, acute lymphosarcoma leukemia, and acute myeloblastic leukemia" (opinion, p. 2). The Court further indicates that cancellation of the words "and anti-tumour" from the specification of appellants' patent application "was arbitrary and capricious." The Court, therefore *reversed* the decision of the District Court holding otherwise, "with leave to the Commissioner to allow an amendment restricting the specification to assertions that are supported by the applicants' proof" (opinion, p. 4).

2. Appellants cannot suffer legal harm because of the Commissioner's action

The Court's opinion does not indicate the Court considered the Commissioner's argument that "[a]ppellants cannot suffer legal harm because of the Commissioner's action," presented on pages 9 through 12 of the "Brief for Appellee." It is believed favorable consideration by the Court of this point would dispose of the appeal by way of affirmance.

3. Request for Clarification of Opinion

On the assumption the Court did consider the above-mentioned point and chose not to discuss the point in its opinion, the Commissioner nevertheless requests clarification of the Court's opinion.

A fair reading of the Court's opinion seemingly indicates that the Commissioner is not required to grant appellants

a patent having a specification containing the language "and anti-tumour." In this respect, this Court has *affirmed* the decision of the District Court. On the other hand, the Court's opinion seemingly indicates that the Commissioner acted in an arbitrary and capricious manner in requiring cancellation of the language "and anti-tumour." In this respect, this Court has *reversed* the decision of the District Court.

It would appear that this Court has not passed on the question decided by the District Court, i.e., whether the language "and anti-tumour" should or should not have been cancelled. Rather, this Court, apparently relying on appellee's oral argument, has indicated in its opinion that the Commissioner rejected "amending language that would restrict the assertion to those uses supported by the proof" (opinion, p. 3). In this respect, the Court has acted *sua sponte* and in so acting passed on a question, not ruled upon by the District Court, *viz.*, whether an amendment which would restrict the assertions to those uses supported by proof is new matter within the meaning of 35 U.S.C. § 132, last sentence.

The Commissioner has no objection, in this case, to the Court's *sua sponte* action as outlined above.[1] However, the Commissioner does not fully understand what is required of him by the Court's opinion and decision. Moreover, the Commissioner does not understand how a *reversal* of the District Court's decision can be predicated upon this Court's *sua sponte* action.

In view of the Court's opinion and decision in this case, the Commissioner is prepared to permit appellants to amend "[t]he paragraph containing the disputed phrase" (opinion, p. 2) to read as follows:

> "*S. Griseus, var. rubidofaciens, strain DS 32,041* differs from the species distinguished by S. A. Waksman with-

[1] See, however, *Camp* v. *Pitts*, 411 U.S. 138 (1973).

in the series of the strains of *S. griseus*, of which none of those hitherto described gives a soluble red pigment comparable to that produced by the strain DS 32,041 nor gives any production of an antibiotic and anti-tumour substances effective in treating certain tumors, namely lymphosarcoma, nephroblastoma, neuroblastoma, acute lymphoblastic leukemia, and acute myeloblastic leukemia, identical to daunorubicin * * *."

If the above-suggested language is what the Court had in mind in granting "leave to the Commissioner to allow an amendment restricting the specification to assertions that are supported by the applicants' proof," (opinion, p. 4), then the Commissioner believes that the last paragraph of the Court's opinion should be amended to read as set forth in Appendix I hereof. In connection with footnote 1 of the opinion, the Court may wish to cite as precedent *Application of Davies*, 475 F.2d 667 (CCPA 1973).

Respectfully submitted,

/s/ JOSEPH F. NAKAMURA
Joseph F. Nakamura
Solicitor
United States Patent Office

/s/ FRED E. MCKELVEY
Fred E. McKelvey
Associate Solicitor
United States Patent Office

December, 1974

APPENDIX I

We therefore conclude that the Commissioner may properly permit an amendment restricting the specification assertions that are supported by the applicants' proof.[1] Spe-

[1] We note, and counsel for the appellee acknowledged at oral argument, that the applicants could refile their application with an amended specification, thereby retaining their filing date and accomplishing the same result.

cifically, the Commissioner is authorized to grant applicants a patent having a specification containing the paragraph:

> "*S. Griseus, var. rubidofaciens, strain DS 32,041* differs from the species distinguished by S. A. Waksman within the series of the strains of *S. griseus,* of which none of those hitherto described gives a soluble red pigment comparable to that produced by the strain DS 32,041 nor gives any production of an antibiotic and anti-tumour substances effective in treating certain tumors, namely lymphosarcoma, nephroblastoma, neuroblastoma, acute lymphoblastic leukemia, and acute myeloblastic leukemia, identical to daunorubicin * * *."

The decision of the Commissioner requiring cancellation of the language "and anti-tumour" and the decision of the District Court are vacated. The matter is remanded to the Commissioner of Patents for further proceedings consistent with this opinion.

Vacated and Remanded

RHONE-POULENC'S PETITION FOR REHEARING IN THE COURT OF APPEALS

(Caption Omitted in Printing)

Appellants respectfully petition, under F.R.A.P. 40, for rehearing and revision of the decision rendered by this Honorable Court on December 3, 1974.

The points which, in the opinion of petitioners, the Court overlooked or misapprehended are as follows:

(1) The Court decided *sua sponte* an issue that had not been decided either by the administrative agency concerned (the Patent Office) or by the District Court.

(2). Asuming *arguendo* that the issue referred to in (1) should have been decided at all by this Court, appellants respectfully submit that it was decided incorrectly.

The Court's Opinion of December 3rd

This Honorable Court was eminently correct in deciding what, in appellants' respectful submission, was the *only* issue properly before the Court on the merits. That was the second of the two issues appearing in the "Statement of the Issues Presented For Review" in the following terms (p. 2 of appellants' opening brief):

> "2. Was the Commissioner's action in requiring Rhone-Poulenc to delete the reference to anti-tumor activity of its antibiotic daunorubicin at page 9, line 15 of the specification of its otherwise allowable patent application arbitrary, capricious and a violation of due process?"

In the paragraph bridging pp. 3 and 4 of the Court's Slipsheet Opinion (SO. 3-4), the Court *correctly* concluded that "the cancellation of the words 'and anti-tumour' by the Patent Office was arbitrary and capricious". Having decided the only issue properly before it—and the only issue that had been decided by the Commissioner on petition [JA 46-47] and by the District Court [JA 14-17]—this Court should have rested instead of *then* going on to give "leave to the Commissioner to allow an amendment restricting the specification to assertions that are supported by the applicants' proof" (SO. 4).

The Argument

In coupling its very proper reversal of the decision below, based on the arbitrary and capricious action of the Patent Office, with the gratuitous suggestion (requirement(?)) of a restrictive amendment, appellants respectfully submit that this Court erred both *procedurally* and substantively.

On the *procedural* aspect, it is well settled that an appellate court should not *sua sponte* render a decision on an issue that has not been decided by the lower tribunal(s). For example, in *Manufacturers' Finance Co.* v. *McKey*, 294

U.S. 442 (1935), the Supreme Court of the United States reversed the Circuit Court of Appeals on the point on which the decrees of the lower courts rested. The Supreme Court then noted that the question or extent of the petitioners' legal rights on *another* point had been neither determined nor considered upon the facts or the applicable law. The Supreme Court held that,

> "The duty and responsibility of that consideration and determination lie primarily with the lower courts; and . . ., should not, we think, be assumed in the first instance by this court." 294 U.S. at 453.

In *Zenith Radio Corp.* v. *Hazeltine Research, Inc.*, 401 U.S. 321, reh. den. 401 U.S. 1015 (1971), the Supreme Court noted that the question of damages sustained by Zenith in the Canadian market had not been passed upon by the trial judge. Significantly, the Supreme Court thereupon noted that,

> ". . . the trial judge made no such findings as to Canada, and we lack power to make them for him." 401 U.S. at 340, n.8.

A similar doctrine applies where an administrative agency is involved. *Camp, Comptroller of the Currency* v. *Pitts*, 411 U.S. 138 (1973). See 411 U.S. at 142-3.

On the *substantive* aspect, little need be said. Appellants respectfully suggest that the Court failed to take sufficiently into account the distinction (well recognized in patent jurisprudence) between, on the one hand, properties that are *inherently* present in a composition of matter otherwise fully disclosed and which therefore an inventor is entitled to *cover* by means of broad nonexclusionary language even though not expressly disclosed in his specification, and on the other hand, properties which not only were neither inherent nor expressly disclosed in his specification but also which could not have been so disclosed without a charge of new matter. These opposites are well illustrated by

Diamond Rubber Co. v. *Consolidated Rubber Tire Co.*, 220 U.S. 428 (1911), especially at pp. 434-437, and *Schriber-Schroth Co.* v. *Cleveland Trust Co.*, 305 U.S. 47 (1938), especially at pp. 57-59.

In other words, under the *Diamond Rubber* doctrine the appellants should not be forced into a position where the usefulness of daunorubicin for any *specific* type of tumor might some day be held to fall outside the *generic* protection afforded by their patent-to-be wholly apart from any particular claim language * that might be employed. The "legal harm" to which appellants might possibly be subjected under such circumstances was fully dealt with in general terms in appellants' opening brief at pp. 13-17 and in more detailed fashion in their reply brief at pp. 3-4.

It follows that the suggested amendatory language of the Court (SO. 2-3) ought not to be imposed upon the appellants insofar as this might involve forcing appellants against their will to recite in the questioned paragraph at p. 9 of their specification the five specific tumors mentioned by the Court, but preceded by the *restrictive* word "namely". Stated differently, the suggestion for revision made by the Court would, in appellants' view, be acceptable if, and only if, instead of using the word "namely", appellants were to be permitted to preface the enumeration of the five specific tumors with the nonlimiting expression "by way of example" or the like.

Conclusion

It is respectfully submitted that this Honorable Court, although correctly deciding the only issue properly before it, departed from sound and orderly judicial practice by going beyond such issue and by rendering a decision on the so-called "new matter" issue, and that in any event the

* Hence even without amendment, appellants' specification is not "overbroad" as intimated by the Court (SO. 3).

Court incorrectly decided the last-mentioned issue. Rehearing and appropriate revision of the decision of December 3, 1974 are therefore respectfully requested.

Respectfully submitted,

ELLSWORTH H. MOSHER
CHARLES A. WENDEL
1911 Jefferson Davis Highway
Suite 600, Crystal Mall One
Arlington, Virginia 22202
(703) 920-8900
Attorneys for Appellants

December 1974

EXAMINER'S AMENDMENT, DATED MARCH 13, 1975

Mailed, March 13, 1975, Group 120

Address Only Commissioner of Patents, Washington, D.C. 20231

In Reply Please Refer To The Following:

Examiner's Name D. Stephens

Gr. Art Un. 125 Filing Date 11-14-68 Serial No. 775,904

Applicant Mancy, Denise et al

Invention Process for the Preparation of Daunorubicin by Cultivating A Streptomyces Species

Paper No. 27
Mailed .....

Stevens, Davis, Miller & Mosher
1911 Jefferson Davis Hwy.
Suite 600 Crystal Mall 1
Arlington, Va. 22202

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Changes and/or Additions to the Application Record Made By The Examiner Upon Allowance

This application is in condition for allowance and the following changes have been made therein by the Examiner. Should the changes be unacceptable to applicant, an appropriate amendment may be proposed *after the Notice of Allowance has been received, as provided under Rule 312.* To ensure consideration of such amendment, it must be submitted on or before remittance of the Base Issue Fee.

Prosecution on the Merits Is Closed. A Notice of Allowance Will Be Mailed In Due Course.

[ ] Note attached Notice of Reference Cited, PO-892, which is part of this communication. The listed references are considered to be pertinent to the claimed invention, but the claims are deemed patentable thereover.

This application is before the Primary Examiner following a decision in *Rhone-Poulenc S.A.* v. *Dann,* — F.2d —, 184 USPQ 196 (4th Cir. 1974), petitions for rehearing by appellant and the Commissioner having been denied (4th Cir. Jan. 30, 1975).

In filing a petition for rehearing in connection with the above-mentioned decision, the Commissioner set forth his understanding of what was required of the Patent Office by the Court's decision. Specifically, the Commissioner set forth in the petition for rehearing the manner in which he believed the paragraph on page 9, lines 11-17 of the specification should be amended in light of the Court's opinion.

In denying both petitions for rehearing, Chief Judge Haynsworth, speaking for the Court, said:

> "Upon consideration of the petition of the Commissioner for rehearing and for revision of the opinion, it appearing from the proposal included in the petition that counsel for petitioner [the Commissioner] clearly

understands the Court's intention, and upon consideration of the appellants' petition for rehearing,

Now, therefore, with the concurrence of Judges Russell and Field, IT IS ORDERED that the petitions be, and hereby are, denied."

In view of the suggestions made by the Commissioner in his petition for rehearing and the Chief Judge's comments, the paragraph on page 9, lines 11-17 of the specification is cancelled and in its place the following language is inserted:

—*S. Griseus, var. rubidofaciens, strain DS 32,041* differs from the species distinguished by S. A. Waksman within the series of the strains of *S. griseus,* of which none of those hitherto described gives a soluble red pigment comparable to that produced by the strain DS 32,041 nor gives any production of an antibiotic and anti-tumour substances effective in treating certain tumors, namely lymphosarcoma, nephroblastoma, neuroblastoma, acute lymphoblastic leukemia, and acute myeloblastic leukemia, identical to daunorubicin (The Actinomycetes, Vol. II, S. A. Waksman, The Williams and Wilkins Company, Baltimore, 1961, pages 141-143).
—.

ORDER OF THE DISTRICT COURT, DATED MARCH 19, 1975

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

RHONE POULENC S.A., DENISE MANCY, LEONE NINET and JEAN PREUD' HOMME, *Plaintiffs*

v.

C. MARSHALL DANN, COMMISSIONER OF PATENTS AND TRADEMARKS, *Defendant*

Civil Action No. 168-73A

ORDER

In view of an "Examiner's Amendment" entered on March 13, 1975, in the file wrapper of plaintiffs' application Serial No. 775,904, it further appearing that the parties agree the "Examiner's Amendment" complies with the

mandate of the U.S. Court of Appeals for the Fourth Circuit in this case, and it still further appearing that further proceedings in this civil action in this court are no longer required, it is this 19th day of March, 1975, ordered that the Clerk is authorized to remove this civil action from the docket if the plaintiffs do not file a timely petition for a writ of certiorari to the Supreme Court of the United States.

/s/ ALBERT V. BRYAN, JR.
Albert V. Bryan, Jr.
United States District Judge

Approved as to form:

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